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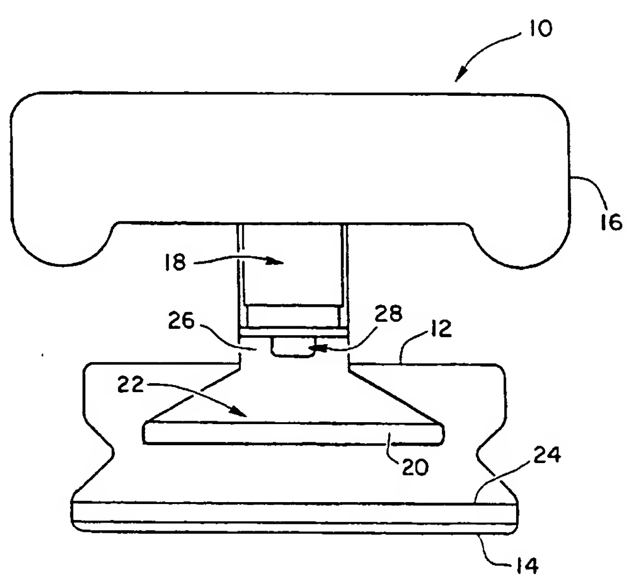
(54) Title: CARDIOPULMONARY RESUSCITATION CHEST COMPRESSION/DECOMPRESSION DEVICE WITH ELECTRONIC STETHOSCOPE



(57) Abstract: A device for performing cardiopulmonary resuscitation on a patient comprises an applicator body that is configured to be adhered to the patient's chest. A handle is coupled to the applicator body to permit the patient's chest to be actively compressed and lifted by pressing and pulling upon the handle. A stethoscope system is operably coupled to the applicator body to sense the patient's heart beat and to disseminate information on the heart beat to a rescuer.

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CARDIOPULMONARY RESUSCITATION CHEST COMPRESSION/DECOMPRESSION DEVICE WITH ELECTRONIC STETHOSCOPE

BACKGROUND OF THE INVENTION

This invention relates generally to the field of cardiopulmonary resuscitation (CPR). More specifically, the invention relates to techniques for determining whether a patient's heart is beating in association with the performance of CPR.

Sudden cardiac arrest is one of the major causes of death for certain age categories worldwide. As such, significant efforts have been expended to increase a patient's chances of survival when faced with cardiac arrest. Probably the most common is the performance of CPR where the patient's chest is repeated compressed, often in combination with patient ventilation.

Another technique that has recently been developed is active compression/decompression (ACD) CPR where the patient's chest is actively pressed and lifted in an alternating manner. By actively lifting the chest, the negative intrathoracic pressure is increased causing more venous blood to flow to the heart and lungs during the decompression phase. Exemplary devices to assist in the performance of ACD CPR include the Ambu® CardioPump™, as well as the devices described in U.S. Patent Nos. 5,645,522 and 5,454,779, the complete disclosures of which are herein incorporated by reference. Such devices have the ability to couple to the patient's chest to facilitate lifting of the chest during the decompression phase.

To augment the duration and extent of negative intrathoracic pressure during the decompression phase of CPR, a pressure-responsive valve may be disposed in the patient's airway. During at least the initial portion of the decompression phase, respiratory gases are prevented from reaching the patient's lungs. In this way, the negative intrathoracic pressure is increased to increase the flow of venous blood to the heart and lungs. Such techniques are described in, for example, U.S. Patent Nos. 5,551,420, 5,692,498, and 6,062,219, the complete disclosure of which is herein incorporated by reference.

This invention is related to other equipment and techniques that may be used by the rescuer when performing CPR. More specifically, the invention relates to the detection of the patient's heart beat in association with the performance of CPR.

SUMMARY OF THE INVENTION

The invention provides for the detection of a patient's heart beat in association with the performance of CPR. Conveniently, the invention may be used in connection with ACD CPR, although the invention is not limited only to such CPR techniques. Further, the invention may be utilized to detect the heart beat before, during and/or after the performance of CPR.

In one embodiment, such features are accomplished by use of a CPR device which comprises an applicator body that is configured to be adhered to the patient's chest. A handle is coupled to the applicator body to permit the patient's chest to be actively compressed and lifted by pressing and pulling upon the handle. A stethoscope system is operably coupled to the applicator body to sense the patient's heart beat and to disseminate information on the heart beat to a rescuer. In this way, the rescuer may utilize the same device that is to be used in performing CPR to also detect the presence or absence of the patient's heartbeat.

In one aspect, the stethoscope system comprises an acoustic transducer to sense low frequency acoustic waves from the beating heart, and an amplifier and a filter to amplify and filter the low frequency acoustic waves. The acoustic signal may then be used to display a visual representation of the heart beat on the handle. For example, the display may comprise a multi-light bar graph, or a single light emitting diode (LED), that progressively illuminates to demonstrate the strength of the signal. In another aspect, the acoustic signal may be presented to the rescuer in audible form. For example, a speaker may be provided on the handle, or headphones may be coupled to the device to permit the rescuer to listen to the amplified and filtered heart beat.

The stethoscope system may be configured in other ways to sense whether the heart is beating. For example, the stethoscope system may include at least one pair of bipolar electrodes that are configured to detect cardiac electrical activity when in contact with the patient's chest. As another example, the stethoscope system may utilize non-electric components, such an acoustic channel in the applicator body that is coupled to an ear piece similar to a traditional stethoscope.

In another aspect, the applicator body is constructed of a flexible material and includes a surface that is adapted to contact the patient's chest. The applicator body also has an open interior permitting the applicator body to act as a vacuum cup. In this way, the patient's chest may be actively lifted when lifting on the handle. The device may further include a compression piston that is disposed to move within the applicator body when

pressing and lifting the handle. The compression piston has a flanged conical portion, with or without a diaphragm attached to the conical portion similar to a conventional stethoscope, that is used to facilitate the capture of acoustic wave transmission from the patient's chest cavity. The compression piston is also used to compress the patient's chest when performing CPR. Conveniently, a compression pad may be disposed within the applicator body. In this way, the compression piston may be used to force the compression pad against the patient's chest when the handle is pressed downward. The compression pad is thus employed to cushion the compression piston as it is forced onto the patient's chest.

In one particular aspect, a force sensor may be employed to measure and display a force applied by the applicator body when pressing downward on the handle. A metronome timing circuit may also be employed to provide visual and audio timing signals to guide the rescuer in performing chest compressions and decompressions. Optionally, the system may be configured to produce voice commands to guide the rescuer during a procedure. For example, voice prompts such as "start CPR", "stop, listen for heart beat", "prepare to shock", "stand clear" and the like may be produced at appropriate times.

Other features that may be added include biosensors, such as biopotential electrodes, defibrillator electrodes, and the like for measuring various patient parameters, such as oxygen concentration of the blood, temperature, ECG, chest wall impedance, evidence that the patient is breathing, and the like. Optionally, this information, along with other information, such as information on the patient's heart beat, may be transmitted from the CPR assistance device to a remote receiver. This may be accomplished by including a transmitter on the assistance device and providing appropriate circuitry to process and send the measured signals.

Conveniently, the CPR assistance devices may be used in connection with air flow regulating systems, such as ventilators, and valves which regulate air flow into and out of the patient during the performance of CPR. The CPR assistance devices may also include a defibrillation system to provide defibrillation energy to the patient.

In another embodiment, a method is provided for performing cardiopulmonary resuscitation on a patient. According to the method, an applicator body is pressed against the patient's sternum to compress the patient's chest. The applicator body is then lifted to lift and actively expand the patient's chest. Periodically, the presence or absence of the patient's heart beat is sensed with a stethoscope system that is coupled to the applicator body. For instance, the heart beat test may be performed before, during and/or after the pressing and lifting steps. Once a regular heart beat is detected, the performance of CPR may be stopped.

In one step, information on the patient's heart beat is visually displayed. Conveniently, this information may be displayed at the top end of the applicator body to permit the rescuer to view information on the heart beat when positioned over the patient. Alternatively, information on the patient's heart beat may be audibly produced. This may be accomplished by using a speaker on the applicator body or by separate head phones.

In another step, the force applied to the patient's sternum by the applicator body may be sensed when pressing down on the application body. The sensed force may then be visually displayed to the rescuer so that the rescuer will know if the applicator body is being pushed too hard or too soft, or lifted too much or too little. Further a mechanism may be provided to sense the depth of chest compression and rise of the decompression. In one aspect, a rhythmic signal is produced with a metronome to facilitate timing of the pressing and the lifting steps. Conveniently, the metronome may be incorporated into the applicator body.

The invention further provides a method for detecting whether a patient's heart is beating. According to the method, the rescuer presses down on a handle that is coupled to an applicator body to move a stethoscope system within the applicator body above the patient's sternum. When desired, the rescuer senses for the patient's heartbeat with the stethoscope system. This may conveniently be accomplished by pressing a switch on the handle to activate a sensing system. Information on the patient's heartbeat is then supplied to the rescuer so that the rescuer can determine whether CPR should continue. Optionally, this information may be provided to the rescuer by voice prompts produced by the stethoscope system.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of one embodiment of a CPR assistance device having an internal stethoscope according to the invention.

Fig. 2 is a bottom view of the CPR assistance device of Fig. 1.

Fig. 3 is a top view of the CPR assistance device of Fig. 1 showing various displays.

Fig. 4 illustrates an alternative set of displays for the CPR assistance device of Fig. 3.

Fig. 5 illustrates an alternative embodiment of a CPR assistance device having an internal stethoscope according to the invention.

Fig. 6 is a bottom view of the CPR assistance device of Fig. 5.

Fig. 7 is a bottom view of still another embodiment of a CPR assistance device having an internal stethoscope according to the invention.

Fig. 8 is a bottom view of a further alternative embodiment of a CPR assistance device having biopotential electrodes and acoustic sensors according to the invention.

Fig. 9 is a bottom view of a embodiment of a disposable applicator body that may be used with a CPR assistance device and which includes removable biopotential electrodes and acoustic sensors according to the invention.

Fig. 10 illustrates an embodiment of a CPR assistance device having accessory electrode pads containing biopotential electrodes and acoustic sensors according to the invention.

Fig. 11 is a cross sectional view of the CPR assistance device of Fig. 10.

Fig. 12 is a bottom view of an embodiment of a CPR assistance device having biopotential electrode rings, a defibrillation active electrode, and an acoustic chamber/transducer according to the invention.

Fig. 13 is a cross sectional side view of the assistance device of Fig. 12 when in a decompressed state.

Fig. 14 illustrates the assistance device of Fig. 13 when in a compressed state, and which further includes a dispersive defibrillation electrode.

Figs. 15A-15C are a flow chart showing an exemplary method for checking the presence or absence of a heart beat when performing CPR.

Fig. 16 is a schematic diagram showing a CPR assistance device and an airflow regulation system according to the invention.

Fig. 17 is a side view of an embodiment of a pneumatic CPR assistance device with a depth and rise compression/decompression sensing mechanism according to the invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The invention provides exemplary devices and techniques for evaluating a patient's heart beat in association with the performance of CPR. This is accomplished by using various non-invasive mechanisms to sense whether the patient's heart is contracting. This may include for, example, a stethoscope that is incorporated into a CPR assistance device to listen to sounds produced by heart contractions. Other examples include an echo cardiogram to visualize the heart, measuring changes in the chest wall impedance, and the

like. These may all be incorporated into or associated with a CPR assistance device. In this way, the same device that is used to facilitate the performance of CPR may also be used to evaluate the patient's heart beat. Advantageously, the heart beat may be evaluated before, during and/or after performing CPR. For example, the presence of a heart beat may be sensed before starting CPR to see if CPR is required. While performing CPR with the assistance device, an evaluation of the heart beat may be performed with the assistance device. In this way, the heart beat may be rapidly evaluated to determine if spontaneous circulation has returned without requiring the removal of the assistance device.

The devices and techniques of the invention will find their greatest use in connection with ACD CPR where the patient's chest is actively compressed and lifted with an assistance device. However, it will be appreciated that the invention is not intended to be limited only to ACD CPR, but may be used with other CPR techniques requiring the use of an assistance device. For example, stethoscopes similar to those described herein could also be incorporated into the Michigan Instrument's Thumper device, the 3M Littmann Electronic Stethoscope, Model 2000, and the like.

Heart beat information may be provided to the rescuer in a variety of formats. For example, information on the heart beat may be provided visually on the assistance device. For instance, a larger and/or brighter signal may be displayed depending on the strength of the heart beat. A display in terms of beats per minute could also be displayed. As another example, information on the heart beat may be provided in audio form. This may produced by an amplified signal from a speaker on the device, from headphones, or the like.

The devices and techniques of the invention may also be used in association with other CPR enhancement techniques. For example, the CPR assistance device may include a force sensor to sense the force being applied to the chest. As another example, the assistance device may include a metronome to assist in the timing of chest compressions. One example of such a metronome is described generally in copending U.S. Application No. 09/532,601, filed March 22, 2000, the complete disclosure of which is herein incorporated by reference. As a further example, the CPR assistance device may include a mechanism for determining the depth of chest compression and the rise of chest decompression.

In one embodiment, the invention may utilize many of the components of the CPR assistance devices described in U.S. Patent Nos. 5,454,779 and 5,646,552, previously incorporated herein by reference. According to the invention, such devices may be modified to include an integrated stethoscope to allow the rescuer to determine if a heartbeat is present prior to performing ACD CPR and/or during or after CPR due to the return of spontaneous

circulation. The assistance device having the stethoscope allows the rescuer to slightly compress the chest allowing a stethoscope bell to be in contact with the patient's skin. The rescuer may then press a button or other actuator on the assistance device handle to activate the stethoscope circuitry (if an electronic stethoscope is used) which transducers any low frequency audio tones transmitted within the chest cavity by heart auscultation. Transmitted tones may be displayed visually by a strength signal bar graph light emitting diodes display, by an audio speaker incorporated within the handle of the assistance device, by a remote audio speaker or head phone or the like. Such a combination of features incorporated into a single assistance device reduces the time and equipment required to intermittently check for heart sounds while using the assistance device during the resuscitation attempt.

Referring now to Fig. 1, one embodiment of a CPR assistance device 10 that is particularly useful with ACD CPR will be described. Device 10 is constructed of an applicator body 12 having a bottom surface 14 (see also Fig. 2) that is adapted to contact and adhere to the patient's chest. Applicator body 12 is constructed of a resilient material so that it will function as a suction cup when applicator body 12 is lifted. Conveniently, a handle 16 is coupled to applicator body 12 to permit applicator body 12 to be forced downward and lifted when performing ACD CPR. More specifically, when handle 16 is pushed downward, applicator body 12 flexes to force air out of the space between applicator body 12 and the patient's chest. When handle 16 is lifted, a vacuum is created between applicator body 12 and the patient's chest to permit the patient's chest to be actively lifted during the decompression phase of CPR. Such a process is described generally in U.S. Patent Nos. 5,454,779 and 5,646,552, previously incorporated herein by reference.

A compression piston 18 is coupled to handle 16 and extends into applicator body 12. Not shown is a recoil spring that is disposed within piston 18. Compression piston 18 is constructed of a hollow cylinder that is flanged at a distal end 20 into a conical shape. Such a configuration forms a stethoscope bell 22 at the distal end of compression piston 18. In one embodiment, stethoscope bell 22 has a diameter of about 4 cm to about 5 cm at distal end 20. The conical shape of bell 22 is used to capture acoustic wave transmission from the chest cavity similar to the bell side of a conventional stethoscope. Bell 22 may be constructed of an open conical member or a conical member enclosed by a diaphragm to aid in the reception of low frequency audible tones. As described hereinafter, the conical shape of bell 22 is further used to increase the surface area of compression piston 18 when used for chest compression. Hence, compression piston 18 is configured to be durable to withstand chest compression forces and to efficiently capture acoustic waves from heart auscultation.

Disposed below stethoscope bell 22 is a compression pad 24 that is connected to applicator body 12 as best shown in Fig. 2. Compression pad 24 is constructed of a resilient material or padding to cushion the forces supplied by compression piston 18 when moved against the patient's chest. To provide the necessary forces, compression piston 18 may be constructed of a rigid material, such as a hard plastic, composite, or the like. By configuring compression pad 24 of the resilient material, the force supplied to the rescuer's chest can be cushioned. As best shown in Fig. 2, compression pad 24 comprises an annular body having tabs that are connected to applicator body 14. In this way, compression pad 24 includes an opening to allow acoustic waves to transmit efficiently into stethoscope bell 22. Hence, compression pad 24 serves both to prevent lesion forming during the performance of CPR as well as to act as an interface between the patient's skin permitting acoustic signals to travel into stethoscope bell 22.

The portion of compression piston 18 above stethoscope bell 22 is cylindrical in geometry and defines an acoustic channel 26 from stethoscope bell 22 up to an acoustic transducer 28. As the low frequency acoustic waves from the beating heart reach the acoustic transducer 28, the acoustic waves are converted into an electrical signal that is transmitted to the appropriate electronics within handle 16 to transmit the heartbeat information to the rescuer as described hereinafter.

The circuitry within handle 16 may include an amplifier and filter to amplify and filter the low frequency acoustic waves obtained from the beating heart. This information may then be displayed visually or audibly. One example of how to display such information is illustrated in Fig. 3 which shows a top end of handle 16. Handle 16 includes a bar graph display 30 that is constructed of a series of light emitting diodes (LEDs). The amplified and filtered signal is used to eliminate one or more of the LEDs depending on the signal strength. For example, when the heart is systolic, the transmitted acoustic wave from the chest cavity will be stronger and thus about seven of ten bars on bar graph display 30 may be illuminated. During diastole, the transmitted acoustic wave from the chest cavity will be weaker and thus about three of the ten bars on the bar graph display may be illuminated. If a rhythm exists, this signal strength cycle on bar graph display 30 may sequentially repeat itself in cadence with the beating heart and thus indicate to the rescuer that a heartbeat exists. Handle 16 may also include an audio microspeaker 32 for audibly reproducing the heartbeat. More specifically, audio tones from heart auscultation may be filtered, amplified and heard by the rescuer via microspeaker 32 in handle 16. Optionally, a remote speaker or head phone may be coupled to handle 16 to permit remote monitoring of the heartbeat. It will further be

appreciated that the visual display may include a single LED to illuminate transduced heart sounds.

To detect the presence of a heartbeat, handle 16 is pushed downward until the stethoscope bell 22 engages compression pad 24 and slightly compresses the patient's chest. A stethoscope activation push button switch 34 is then switched on to activate the stethoscope circuitry. The acoustic waves from the heart are then displayed on bar graph display 30 or audibly replicated by microspeaker 32 as just described. After detecting for the heartbeat, button 32 may be switched off. This process may be repeated as many times as needed in order to check for the presence of a heartbeat.

Optionally, handle 16 may include a compression/decompression force indicator 36 to transmit information to the rescuer about the relative amount of downward or upward force applied to the patient when performing ACD CPR. To measure the applied force, one or more transducers may be placed at appropriate locations within applicator body 12 to sense the downward or upward force being applied by the rescuer. Appropriate circuitry may be coupled to the transducers to produce the appropriate signal on force indicator 36. Merely by way of example, force indicator 36 may comprise different colored LEDs that illuminate when the adequate downward or upward force is applied to the patient. Conveniently, this may be calibrated according to the patient's weight. With this configuration, the rescuer may select patient size, i.e., pediatric, small adult, medium adult, large adult, extra large adult, and the like, through a switch setting (not shown) on handle 16. In this way, regardless of patient size, the rescuer will be able to determine whether or not he or she is applying the necessary downward or upward force to maximize cardiopulmonary resuscitation.

Although not shown, device 10 may include a mechanism for detecting the depth of chest compression and rise of chest decompression. Such a mechanism may be similar to that described in connection with Fig. 17. With such a sensing mechanism, handle 16 may include a distance sensor to indicate the depth or rise. This may be accomplished in numerical form, or by simply lighting a series of LEDs relative to a baseline level. As another option a set of LEDs may be lighted once an appropriate chest compression or decompression distance has been achieved.

Optionally, handle 16 may also include a metronome LED 38 and a metronome activation push button switch 40. Handle 16 may also include appropriate metronome timing circuitry to provide the rescuer with visual timing signals when switch 40 is actuated to synchronize the delivery of CPR. Conveniently, the metronome signals may

also be produced audibly, e.g., by using the microspeaker 32. In one alternative, voice prompting circuitry may be incorporated into handle 16 to guide the rescuer through a CPR procedure.

Although not shown, a power source may be integrated into handle 16 to power the stethoscope amplification and display circuitry as well as the compression/decompression force indicator and the metronome timing circuitry. Conveniently, the power source may comprise a rechargeable battery, such as a nickel cadmium (NiCd) battery or the like. In this way, device 10 may easily be recharged from a standard 115 VAC wall outlet by utilizing a DC power pack. Recharging may also occur by utilizing an automobile cigarette lighter power adapter.

As previously described, force indicator 36 may be configured to illuminate only when an adequate downward or upward force is applied to the patient. This may be done using a downward or upward arrow as shown. Alternatively, as shown in Fig. 4, the displays on handle 16 may be modified to include an alternative compression/decompression electronic force indicator 42. This force indicator is similar to bar graph display 30 in that the number of LEDs that are lighted depends on the applied downward or upward force. In this way, the rescuer is provided additional information as to the amount of applied force, rather than simply knowing whether a sufficient force has been applied. The other components on handle 16 may be similar to those previously described in connection with Fig. 3.

Shown in Figs. 5 and 6 is an alternative embodiment of a CPR assistance device 44. Assistance device 44 has many components which are identical to those previously described in connection with CPR assistance device 10. Accordingly, similar components will utilize the same reference numerals previously described in connection with CPR assistance device 10. CPR assistance device 44 differs from assistance device 10 in that a compression pad ring 46 is coupled directly to distal end 20 of stethoscope bell 22. Also, CPR assistance device 44 includes a diaphragm membrane 48 that is disposed across stethoscope bell 22 similar to a conventional stethoscope. In use, handle 16 is lowered to place stethoscope bell 22 against the user's chest. Once in contact with the chest, the patient's heartbeat may be monitored. To perform CPR, compression piston 18 is forced downward onto the patient's chest by applying a force to handle 16. During decompression, handle 16 is lifted while applicator body 12 is suctioned to the chest to actively lift the patient's chest. When stethoscope bell 22 is forced against the chest, compression pad ring 46 serves as a cushion to prevent the formation of lesions on the patient's chest.

Another embodiment of a CPR assistance device 50 is illustrated in Fig. 7. Some of the elements of assistance device 50 may be similar to those previously described in connection with assistance device 44 and will therefore use the same reference numerals. Assistance device 50 includes two pairs of bipolar electrodes 52 that are accessible through compression pad ring 46. The two electrode pairs create a bipolar electrode configuration that may be used to detect cardiac electrical activity when stethoscope bell 22 is in contact with the patient's chest. The electrical activity may be displayed on a bar graph signal strength meter located on handle 16 in a manner similar to bar graph display 30 of device 10 as previously described. Although shown with two electrode pairs, it will be appreciated that other configurations of electrode pairs may be employed to detect electrical cardiac activity.

Although not shown, it will be appreciated that any of the CPR assistance devices described herein may be modified to have a non-electronic stethoscope. Such an embodiment may utilize compression piston 18 as an acoustic transmission tube similar to a conventional stethoscope that connects to acoustic channel 26. The acoustic channel may then travel through the acoustic tube to a rescuer's ear piece that is coupled to the assistance device.

Fig. 8 illustrates another embodiment of a CPR assistance device 60. Device 60 comprises an applicator body 62 that is placed against the patient's chest in a manner similar to other embodiments. A handle 64 that is coupled to a piston (hidden from view) is used to force the piston against the patient's chest and to lift applicator body 62 in a manner similar to other embodiments. Applicator body 62 includes a compression pad 66 that cushions to impact of the piston a manner similar to that previously described. Compression pad 66 further includes a set of acoustic transducers 68 that are molded into support arms 70. When assistance device 60 is placed onto a patient, transducers 68 are able to detect the patient's heart beat. Wiring (not shown) extends from transducers 68 to handle 64 so that information on the patient's heart beat may be displayed on handle 64 in a manner similar to other embodiments.

Support arms 70 further include a set of biopotential electrodes 72 that are placed into contact with the patient's chest when applicator body 62 is placed onto the chest. Electrodes 72 may be used to take biomedical measurements, such as ECG, to determine if the patient is breathing, to determine chest wall impedance, to sense modifications in blood flow, and the like. Example of biopotential electrodes include PALS – Neurostimulation electrodes, commercially available from Axelguard Manufacturing, Fallbrook, CA. Circuitry

and displays may be provided to permit processing and display of the measurements from handle 64.

Fig. 9 illustrates a disposable applicator body 76 that may be used with any of the CPR assistance devices described herein. Applicator body 76 is configured to be coupled to a handle having a compression piston which is similar to those described herein. Applicator body 76 is removable from the handle so that it may be removed and disposed of following a procedure. Applicator body includes a compression pad 78 similar to other embodiments to cushion the impact of the compression piston. Associated with applicator body 76 are a set of removable side flaps 79 that each include an acoustic transducer 80 and a biopotential electrode 82. Conveniently, side flaps 79 may be molded to applicator body 76. Side flaps 79 may include an adhesive or other removable strip that protects transducer 80 and electrode 82 until removed just prior to a procedure. Although not shown, appropriate wires may be provided to electrically connect transducers 80 and electrodes 82 to circuitry within the CPR assistance device in a manner similar to other embodiments.

Fig. 10 illustrates a CPR assistance device 84 having an applicator body 86 and a handle 88 that operates a compression piston (not shown) in a manner similar to the other embodiments described herein. Device 84 may optionally be used with an accessory device 90 having a pair of accessory pads 92 that may be constructed of a foam padding and may each include a biopotential electrode 94 and an acoustic transducer 96 as best shown in Fig. 11. Pads 92 include wiring 98 and a connector 100 that permit electrodes 94 and transducers 96 to be electrically coupled to circuitry within handle 88 so that signals may be sent to and received from these components in a manner similar to that previously described.

With such a configuration, the rescuer may place pads 92 onto the patient's chest as shown in Fig. 10. Conveniently, pads 92 may include an adhesive 102 to adhere pads 92 to the chest. Connector 100 is plugged into handle 88, and controls and displays on handle 88 may be used to process and display signals from transducers 96 and electrodes 94. Conveniently, pads 92 may be configured as active and dispersive electrodes for defibrillation. In this way, controls may be provided on handle 88 so that a defibrillating shock or other electrical treatment, such as phrenic nerve stimulation, may be provided to the patient. CPR may be performed by pushing and pulling handle 88 in a manner similar to other embodiments. At any time, the patient's heart beat may be evaluated using transducers 96 and appropriate displays on handle 88 in a manner similar to that previously described.

Figs. 12-14 illustrate another embodiment of a CPR assistance device 100 that comprises an applicator body 102 and a handle 104 that is used to move a compression piston

106 in a manner similar to other embodiments. Coupled to piston 106 is a compression pad 108 having a pair of biopotential electrode rings 110 and 112 that are used to take biomedical measurements, such as oxygen concentration of the blood, temperature, chest wall impedance and ECG when placed against the patient's chest. Pad 108 also includes an active defibrillation electrode 114 that is used with a dispersive defibrillation electrode 116 (see Fig. 14) that is coupled to handle 104. Handle 104 conveniently includes a port into which electrode 116 may be inserted. Handle 104 may also include appropriate displays and controls to facilitate the application of defibrillation energy to the patient.

Pad 108 surrounds an acoustic chamber 118 in which is disposed an acoustic transducer 120. An acoustic membrane 122 may cover chamber 118 to prevent suction during decompression of the patient's chest. Transducer 120 is coupled to circuitry that permits information on the patient' heartbeat to be measured when handle 104 is moved from the decompressed position of Fig. 13 to the compressed position of Fig. 14 where the acoustic chamber 118 is adjacent the patient's chest.

One advantage of incorporating defibrillation electrode 114 on pad 108 is that defibrillation energy may be decreased by compressing the chest with piston 106. This occurs by two mechanisms. First, the distance between the heart and the active defibrillation electrode 114 is decreased, thus reducing tissue/bone resistance. Second, the resistance between active electrode 114 and the patient's skin is decreased by increasing the conductive surface area of the active electrode 114.

In another aspect, any of the CPR assistance devices described herein may be configured to measure and transmit sensory information to a remote device. Such information may include, for example, ECG, heart beats, pH, oxygen concentration, temperature, and the like. This information may be measured using biosensors, such as biopotential electrodes, temperature strips, oxygen saturation monitors, and the like. The measured information is then processed to a form suitable for transmission. The information may be transmitted using a variety of transmitters and receivers, including for example, by cordless or wireless technology, by RF transmission to a remote device (similar to a cordless phone or other telemetry devices), and the like. Various transceivers may also be used so that the assistance device may receive information as well as transmit information.

Referring now to Figs. 15A-15C, an exemplary method for detecting the presence or absence of a heart beat in association with a CPR procedure will be described. In so doing, it will be appreciated that such a method may be utilized with any of the embodiments of CPR assistance devices described herein. The process begins at step 200

and utilizes a CPR assistance device having an applicator body. The CPR assistance device may optionally include a voice prompting system having a speaker that provides various voice prompts; however, the process may be performed without voice prompts. With such a configuration, a voice prompt switch may be turned on as shown in step 202. The voice prompt requests that the device be placed onto the patient's sternum as shown in step 204. Preferably, the patient's chest will be bare to facilitate adherence of the applicator body to the patient's chest to permit the chest to be actively lifted. Another voice prompt requests the rescuer to listen for a heart beat using the CPR assistance device's stethoscope as shown in step 204. This may be accomplished by pressing the handle of the assistance device downward to contact the stethoscope to the chest. If an electronic stethoscope is used, the electronics may be switched on to detect the presence of a heart beat. A voice prompt further asks whether a heart beat is present as shown in step 208. A response may be input into the assistance device by a keypad, voice recognition software, or the like. If a heart beat is displayed, the process continues to step 210 where a voice prompt requests that the device be removed from the chest.

A voice prompt may optionally ask whether the patient is breathing as shown in step 212. If so, another voice prompt may be given to stop ventilation as shown in step 214, and the process ends at step 216. If the patient is not breathing, the process proceeds to step 218 where a voice prompt requests that ventilation continue. A timer that is set to a certain time is then actuated at step 220. At the expiration of the timer, the process reverts back to step 212 where patient breathing is again evaluated.

If a heart beat is not detected at step 208, the performance of CPR begins. Optionally, a metronome on the assistance device may be actuated as shown in step 222, and a voice prompt may request that CPR begin as shown in step 224. The handle is then pressed downward and lifted in an alternating manner to compress and decompress the chest. Optionally, the applied downward and upward force may be measured and displayed while the rescuer is performing CPR. At any time during the performance of CPR, the rescuer may press down on the handle until the stethoscope bell comes into contact with the patient's chest. As the handle is pressed downward, the applicator body flexes to permit the compression piston to move downward within the applicator body until coming into contact with the patient's chest. The stethoscope is then turned on and the presence of a heart beat is monitored in a manner similar to that previously described.

While performing CPR, various voice prompts may be given regarding the manner of chest compressions and decompressions. For example, in step 226 an evaluation is

made by the assistance device as to the rate of chest compression. If too fast, a voice prompt requests the rescuer to slow down as shown in step 228, and if too slow, a voice prompt requests the rescuer to speed up as shown in step 230. In step 232 an evaluation is made by the assistance device as to the distance of chest compression. If too far, a voice prompt requests the rescuer to compress less shown in step 234, and if not far enough, a voice prompt requests the rescuer to compress more as shown in step 236. In step 238 an evaluation is made by the assistance device as to the distance of chest decompression. If too far, a voice prompt requests the rescuer to decompress less shown in step 240, and if not far enough, a voice prompt requests the rescuer to decompress more as shown in step 242.

The assistance device may optionally include a timer that may be set for a certain time as shown in step 244. If the time has not expired, CPR is continued and steps 226-242 are repeated. Once the timer expires, the process may optionally proceeds to step 246 where a voice prompt requests that the shock energy be set. At step 248, another voice prompt requests that the area be cleared. A timer is then automatically set in step 250 and the energy is released upon expiration of the timer as shown in step 252. A voice prompt may then request the rescuer to check for the presence of a heart beat as shown in step 254. If present, the process reverts back to step 210. If no heart beat is detected, a counter is incremented at step 256 and is checked at step 258 to see if the counter has reached a threshold value. If not, defibrillation is again repeated. If so , the counter is reset to zero at step 260 and a voice prompt requests that CPR continue at step 262. The process then proceeds back to step 226 where CPR is repeated.

The CPR assistance devices and associated procedures described herein may be used in connection with a variety of ventilation and air regulation systems that regulate airflow to and/or from the patient during resuscitation. Merely by way of example, such systems may include those described in U.S. Patent Nos. 6,062,219, 5,692,498, and 5,551,420, and copending U.S. Patent Application Serial Nos. 09/546,252, filed April 10, 2000, and ____________________, filed on the same date as the present application (Attorney Docket No. 16354-000113), the complete disclosures of which are herein incorporated by reference.

Such a combined system is illustrated in Fig. 16 which shows a CPR assistance device 300 that is representative of any of the assistance devices described herein. Coupled to the patient's airway is a facial mask 302 to which is coupled a compressible bag 304 so that the patient may be ventilated. Disposed between mask 302 and bag 304 is a valve system 306 that is representative of any of the valve systems described in the above

paragraph. Valve system 306 includes a pressure responsive valve 308 that opens to permit respiratory gases to flow to the lungs through valve 308 once a certain negative intrathoracic pressure is created in the patient's chest during decompression when assistance device 300 is pulled upward by the rescuer. In some cases, valve system 306 may be configured to prevent respiratory gases from escaping the chest during compression when assistance device 300 is pressed downward. Once a threshold pressure is created, gases are permitted to exit the patient through valve system 306. To ventilate the patient, bag 304 is squeezed to forced air through valve system 306 and into the patient's lungs.

Another embodiment of a CPR assistance device 320 is illustrated in Fig. 17. Device 320 is similar to the other assistance devices described herein but uses a pneumatic system 322 to reduce user fatigue during CPR. Device 320 comprises an applicator body 324 that may be similar to the applicator bodies of other embodiment. Applicator body 324 includes a compression piston 326 that is forced against the chest to perform chest compressions. In so doing, applicator body 324 compresses. When compression piston 326 moves upward, applicator body 324 is suctioned to the chest and aids in actively lifting the chest. Optionally a stethoscope may be incorporated into piston 326 in a manner similar to other embodiments.

Compression piston 326 slides within a piston housing 328 that in turn in coupled to a handle 330. A pneumatic input port 332 and an output port 334 are provided in housing so that pressures within housing 328 may be manipulated. In so doing, compression piston 324 and applicator body 324 may be moved up and down. To manipulate the pressures within housing 328, ports 332 and 334 may be coupled to a compressed air source that may be part of a controller. For example, the compressed air source may comprise portable air tanks or a gas and/or battery powdered air compressor that are part of the controller.

Handle 330 includes circuitry which is electrically connected to the controller by a cable 335. The electronic circuitry within handle 330 is connected to a linear variable differential transformer 336 that monitors movement of compression piston 326. This information is sent to the controller to control movement of piston 326.

In use, the rescuer places device 320 on the patient's chest, and using controls on handle 330 zeros or calibrates the device. An "on" switch is activated and the user holds device 320 stationary while piston 326 and applicator body 324 move up and down due to operation of pneumatic system 322. Transformer 336 determines the depth of compression or rise of decompression based on the linear distance piston 326 travels. The rescuer may adjust

the depth or rise by selecting an increase or decrease button on handle 330. Conveniently, device 320 may be used for standard or ACD CPR in compression mode only, decompression mode only, or both modes sequentially by varying the movement of piston 326.

Device 320 may also include a mechanism to incrementally increase the depth of chest compression over time until reaching a target depth. For example, the depth of compression for the patient's chest may be determined to be about 5 cm. For the first 30 to 60 seconds of chest compressions, the pneumatic device may automatically compresses the chest 2 cm for the first 10 seconds, 3 cm for the next 10 seconds, 4 cm for the next ten seconds, and continuing on up to the desired depth of compression of 5 cm. This sequence of compression steps may occur from 30 seconds to about 2 minutes but ideally it will occur within about 60 seconds. However, it will be appreciated that other timing sequences may be used. Such a process allows the chest compliance to adapt to chest compressions in an attempt to avoid breaking ribs.

In another aspect, device 320 may include a support mechanism to hold the device 320 stationary over the patient's chest so the rescuer is free to ventilate the patient. Such a device would have sufficient structure to hold the device stationary as the pneumatics compress and decompress the chest.

The invention has now been described in detail for purposes of clarity of understanding. However, it will be appreciated that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A device for performing cardiopulmonary resuscitation on a patient, the device comprising:

an applicator body that is configured to be adhered to the patient's chest;

a handle coupled to the applicator body to permit the patient's chest to be actively compressed and lifted by pressing and pulling upon the handle;

means coupled to the applicator body to sense contraction of the patient's heart; and

means for disseminating information on the heart beat to a rescuer.

2. A device as in claim 1, wherein the means for disseminating comprises an amplifier and filter to amplify and filter low frequency acoustic waves from the beating heart.

3. A device as in claim 1, wherein the means for disseminating comprises a visual display on the handle to visually display the information on the heart beat.

4. A device as in claim 1, wherein the means for disseminating comprises an audio speaker on the handle to produce an audible signal to convey the information on the heart beat.

5. A device as in claim 1, wherein the means for disseminating comprises a remote audio device to remotely produce an audible signal to convey information on the heart beat.

6. A device as in claim 1, wherein the means for sensing comprises an electronic stethoscope.

7. A device as in claim 6, wherein the electronic stethoscope comprises an acoustic transducer.

8. A device as in claim 1, wherein the electronic stethoscope comprises at least one pair of bipolar electrodes that are configured to detect cardiac electrical activity when in contact with the patient's chest.

9. A device as in claim 1, wherein the means for sensing comprises a non-electronic stethoscope, and wherein the means for disseminating comprises an acoustic channel coupled to an ear piece.

10. A device as in claim 1, wherein the applicator body is flexible and includes a surface that is adapted to contact the patient's chest, and wherein the applicator body has an open interior permitting the applicator body to act as a vacuum cup.

11. A device as in claim 1, further comprising a compression piston disposed to move within the applicator body when pressing and lifting the handle, the compression piston having a flanged conical portion that is configured to facilitate the capture of acoustic wave transmission from the patient's chest cavity.

12. A device as in claim 11, wherein the means for sensing the patient's heart beat is disposed within the conical portion.

13. A device as in claim 11, further comprising a compression pad disposed within the applicator body such that the compression piston forces the compression pad against the patient's chest when the handle is pressed downward.

14. A device as in claim 1, further comprising means for measuring and displaying a force applied by the applicator body when pressing downward on the handle.

15. A device as in claim 1, further comprising a metronome timing circuit to provide visual and audio timing signals.

16. A device as in claim 1, further comprising an audio prompting system to provide audio instructions relating to the performance of cardio pulmonary resuscitation.

17. A device as in claim 1, further comprising a defibrillation system to provide defibrillation energy to the patient.

18. A device as in claim 1, further comprising a biosensor to measure biomedical information on the patient.

19. A device as in claim 1, further comprising a transceiver that is capable of transmitting the biomedical information to a remote receiver or receiving information from the receiver.

20. A device as in claim 1, further comprising means for measuring and displaying vertical distances traveled by the applicator body when pressuring downward or lifted upward on the handle.

21. A device for performing cardiopulmonary resuscitation on a patient, the device comprising:

an applicator body that is configured to be adhered to the patient's chest;

a handle coupled to the applicator body to permit the patient's chest to be actively compressed and lifted by pressing and pulling upon the handle; and

a stethoscope system operably coupled to the applicator body to sense the patient's heart beat and to disseminate information on the heart beat to a rescuer.

22. A device as in claim 21, wherein the stethoscope system comprises an acoustic transducer to sense low frequency acoustic waves from the beating heart, and an amplifier and a filter to amplify and filter the low frequency acoustic waves.

23. A device as in claim 21, wherein the stethoscope system comprises a visual display on the handle to visually display the information on the heart beat.

24. A device as in claim 21, wherein the stethoscope system comprises an audio speaker on the handle to produce an audible signal to convey the information on the heart beat.

25. A device as in claim 21, wherein the stethoscope system comprises a remote audio device to remotely produce an audible signal to convey information on the heart beat.

26. A device as in claim 21, wherein the stethoscope system comprises at least one pair of bipolar electrodes that are configured to detect cardiac electrical activity when in contact with the patient's chest.

27. A device as in claim 21, wherein the stethoscope system comprises an acoustic channel in the applicator body that is coupled to an ear piece.

28. A device as in claim 21, wherein the applicator body is flexible and includes a surface that is adapted to contact the patient's chest, and wherein the applicator body has an open interior permitting the applicator body to act as a vacuum cup.

29. A device as in claim 21, further comprising a compression piston disposed to move within the applicator body when pressing and lifting the handle, the compression piston having a flanged conical portion that is configured to facilitate the capture of acoustic wave transmission from the patient's chest cavity.

30. A device as in claim 29, further comprising a compression pad disposed within the applicator body such that the compression piston forces the compression pad against the patient's chest when the handle is pressed downward.

31. A device as in claim 21, further comprising means for measuring and displaying a force applied by the applicator body when pressing downward on the handle.

32. A device as in claim 21, further comprising a metronome timing circuit to provide visual and audio timing signals.

33. A device as in claim 21, further comprising an audio prompting system to provide audio instructions relating to the performance of cardio pulmonary resuscitation.

34. A device as in claim 21, further comprising a defibrillation system to provide defibrillation energy to the patient.

35. A device as in claim 21, further comprising a biosensor to measure biomedical information on the patient.

36. A device as in claim 21, further comprising a transceiver to transmit or receive the biomedical information to or from a remote receiver.

37. A method for performing cardiopulmonary resuscitation on a patient, the method comprising:

pressing an applicator body against the patient's sternum to compress the patient's chest;

lifting the applicator body that is adhered to the patient's chest to actively expand the patient's chest; and

periodically sensing for the patient's heart beat with a stethoscope system that is coupled to the applicator body.

38. A method as in claim 37, further comprising visually displaying information on the patient's heart beat with the stethoscope system.

39. A method as in claim 37, further comprising audibly producing information on the patient's heart beat with the stethoscope system.

40. A method as in claim 37, further comprising sensing the force applied to the patient's sternum by the applicator body during the pressing step with a force sensor and visually displaying information on the applied force.

41. A method as in claim 37, further comprising producing a rhythmic signal with a metronome to facilitate timing of the pressing and the lifting steps.

42. A method as in claim 37, further comprising producing audio prompts with an audio prompting system to facilitate the performance of cardio pulmonary resuscitation.

43. A method as in claim 37, further comprising providing defibrillation energy to the patient using a defibrillation system that is coupled to the applicator body.

44. A method as in claim 37, further comprising measuring biomedical information using a sensor that is coupled to the applicator body.

45. A method as in claim 37, further comprising transmitting the biomedical information to a remote receiver or receiving information from a remote transmitter.

46. A method as in claim 37, further comprising preventing respiratory gases from entering the patient's lungs during expansion of the patient's chest until a certain negative intrathoracic pressure is achieved.

47. A method as in claim 37, further comprising preventing respiratory gases from exiting the patient's lungs during compression of the patient's chest until a certain positive intrathoracic pressure is achieved.

48. A method for detecting whether a patient's heart is beating, the method comprising:

pressing down on a handle that is coupled to an applicator body to move a stethoscope system within the applicator body above the patient's sternum;

sensing for the patient's heartbeat with the stethoscope system; and

disseminating information on the patient's heartbeat to a rescuer.

49. A system for performing cardiopulmonary resuscitation on a patient, the device comprising:

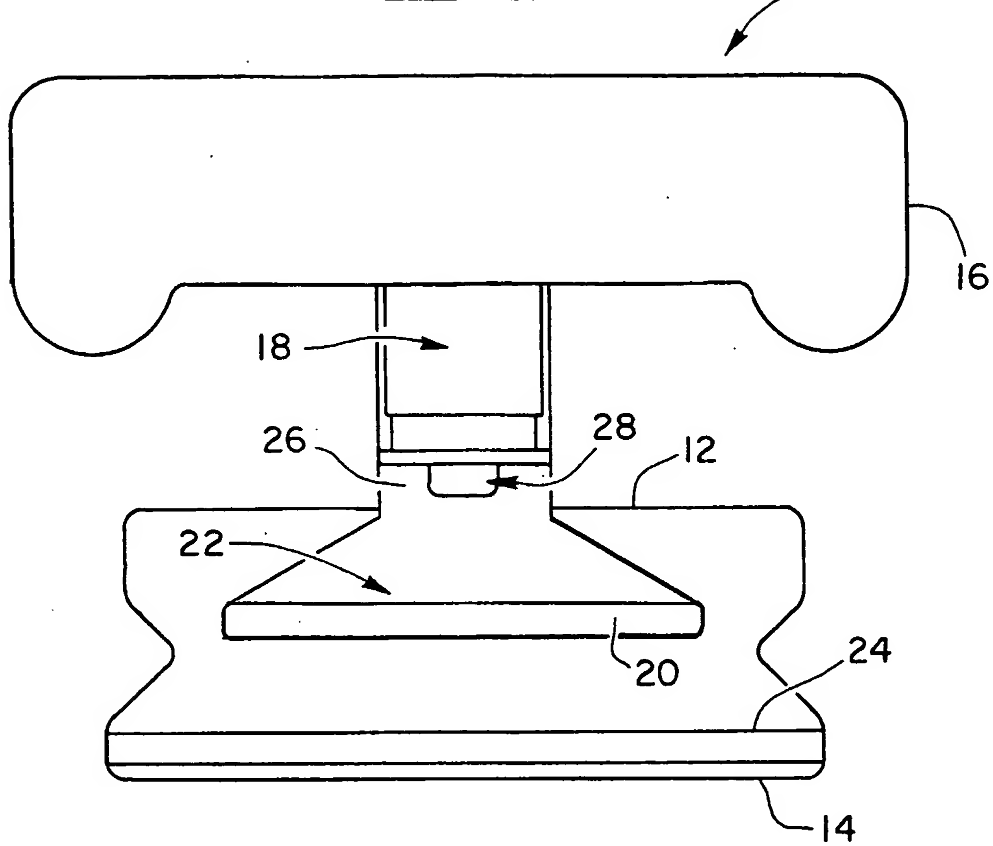
an applicator body that is configured to be adhered to the patient's chest;

a handle coupled to the applicator body to permit the patient's chest to be actively compressed and lifted by pressing and pulling upon the handle;

a stethoscope system operably coupled to the applicator body to sense the patient's heart beat and to disseminate information on the heart beat to a rescuer; and

an air flow regulation system having an interface that is adapted to be coupled to the patient's airway and a pressure responsive inflow valve that is adapted to prevent respiratory gases from flowing to the patient's lungs during lifting of the patient's chest until a certain negative intrathoracic pressure is achieved.

Fig. 1



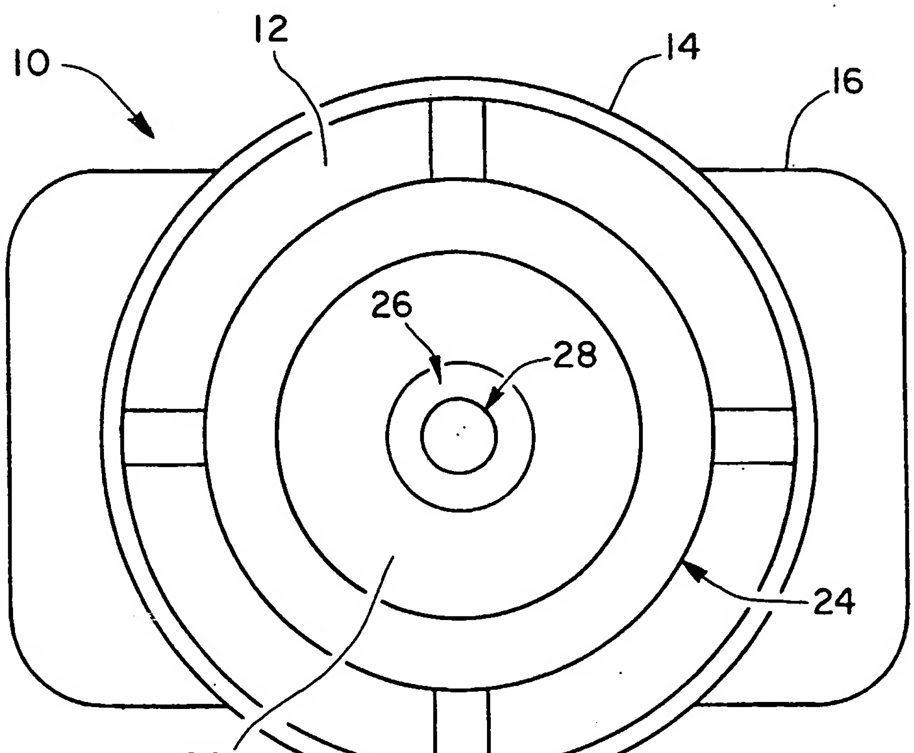
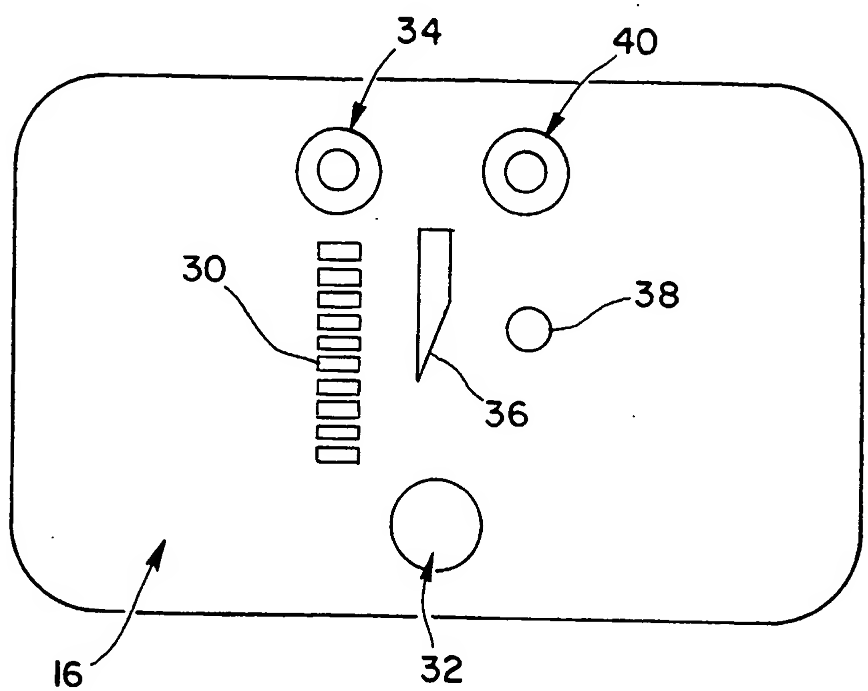


Fig. 2

Fig. 3



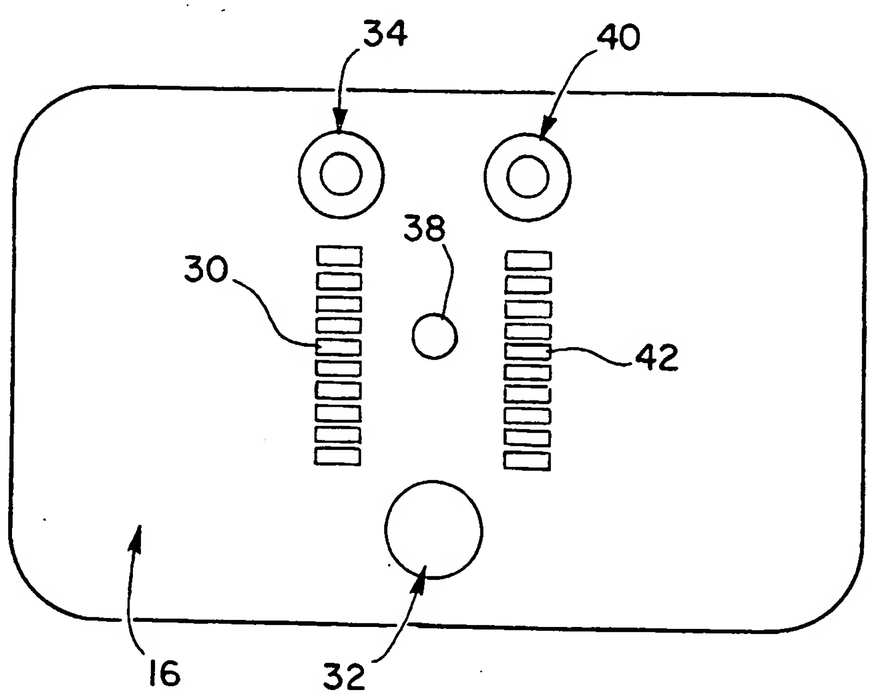


Fig. 4

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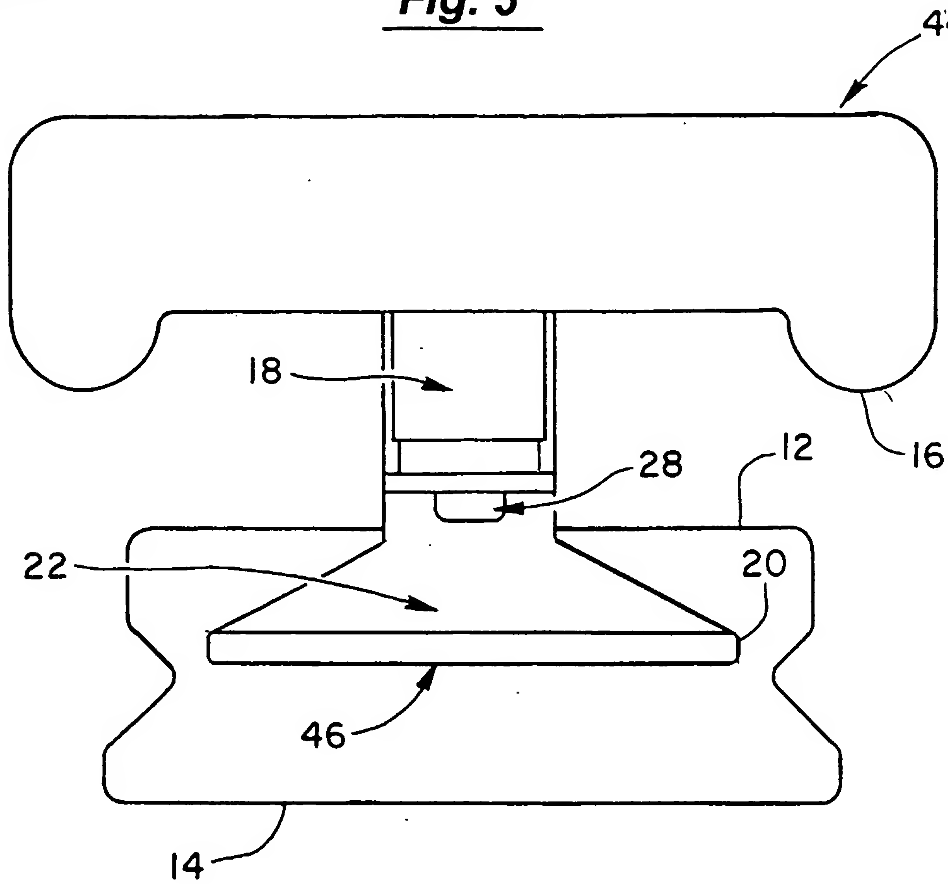
Fig. 5



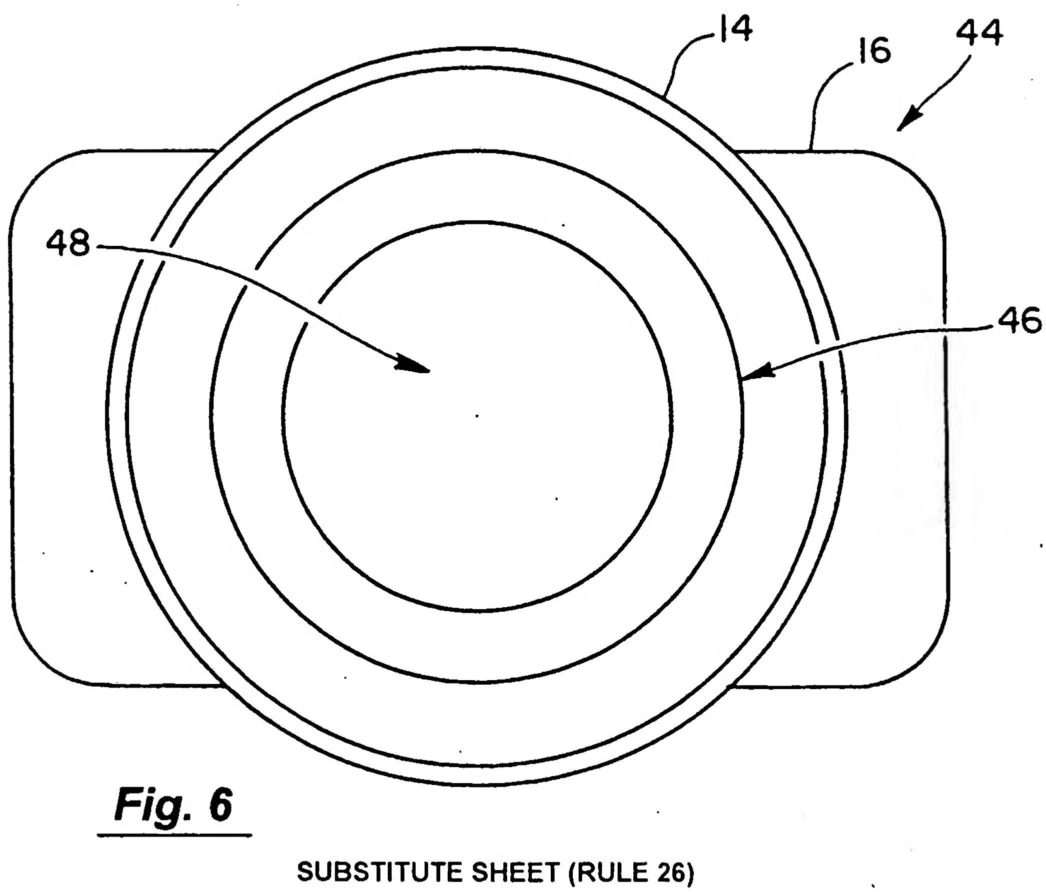


Fig. 6

SUBSTITUTE SHEET (RULE 26)

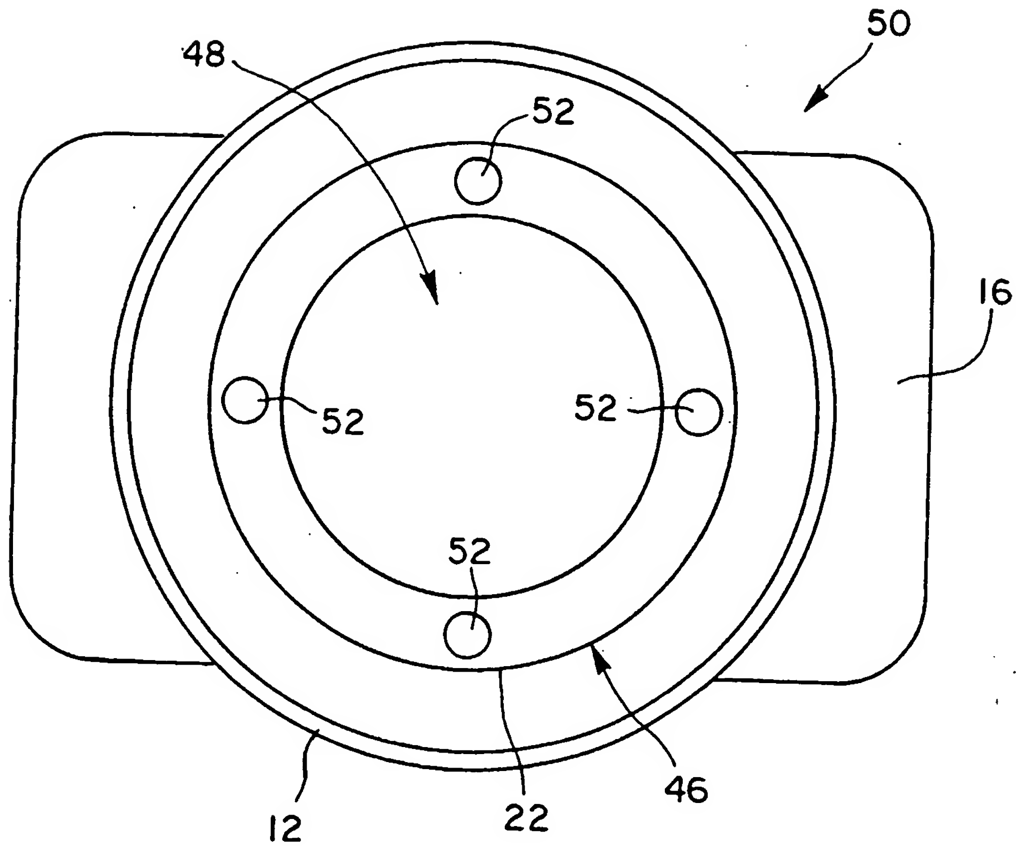
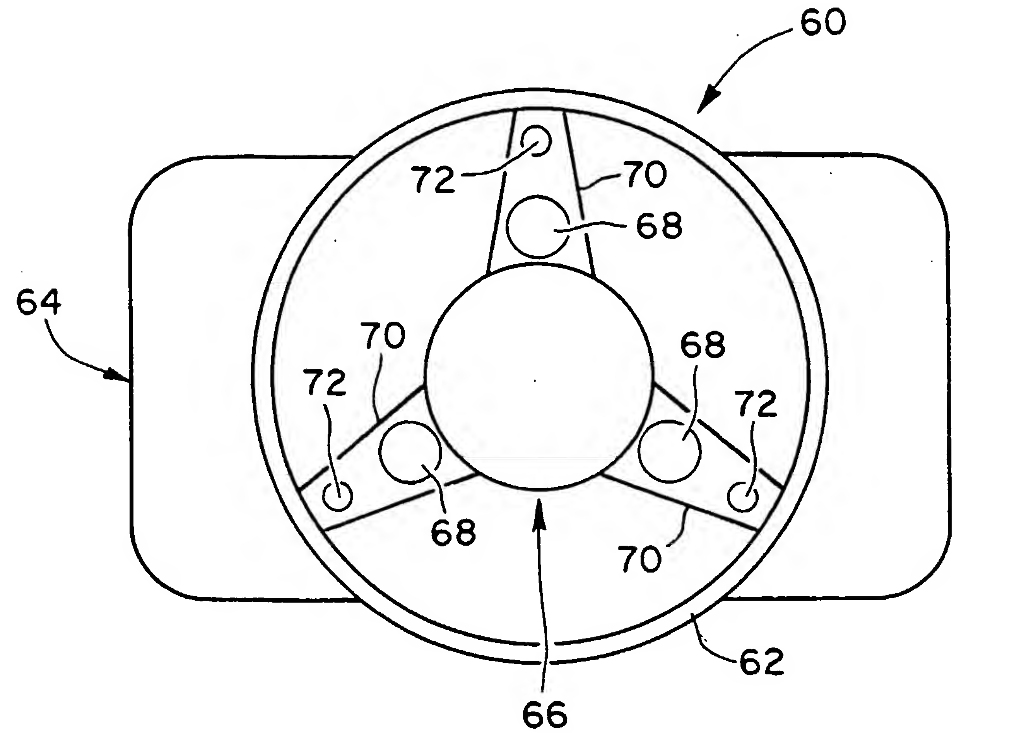


Fig. 7

Fig. 8



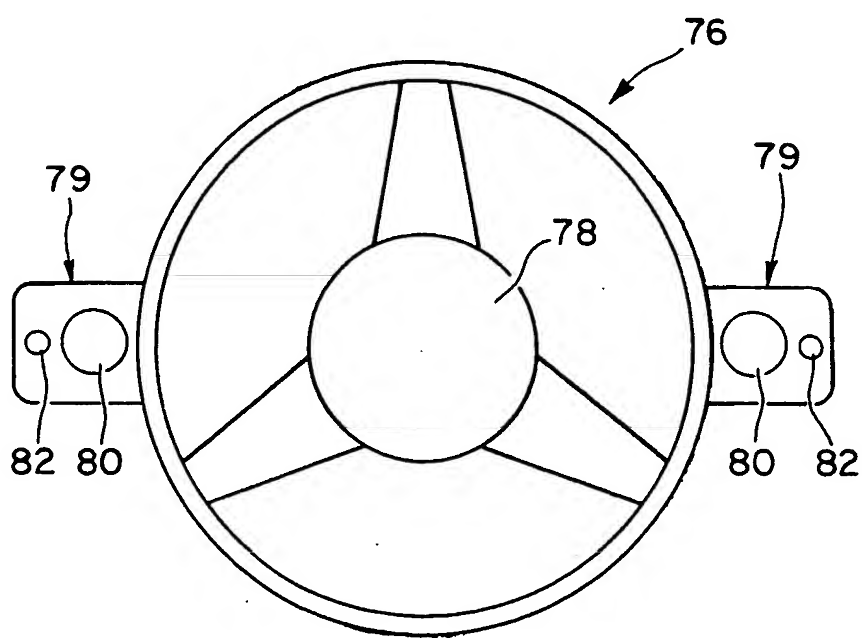


Fig. 9

Fig. 10

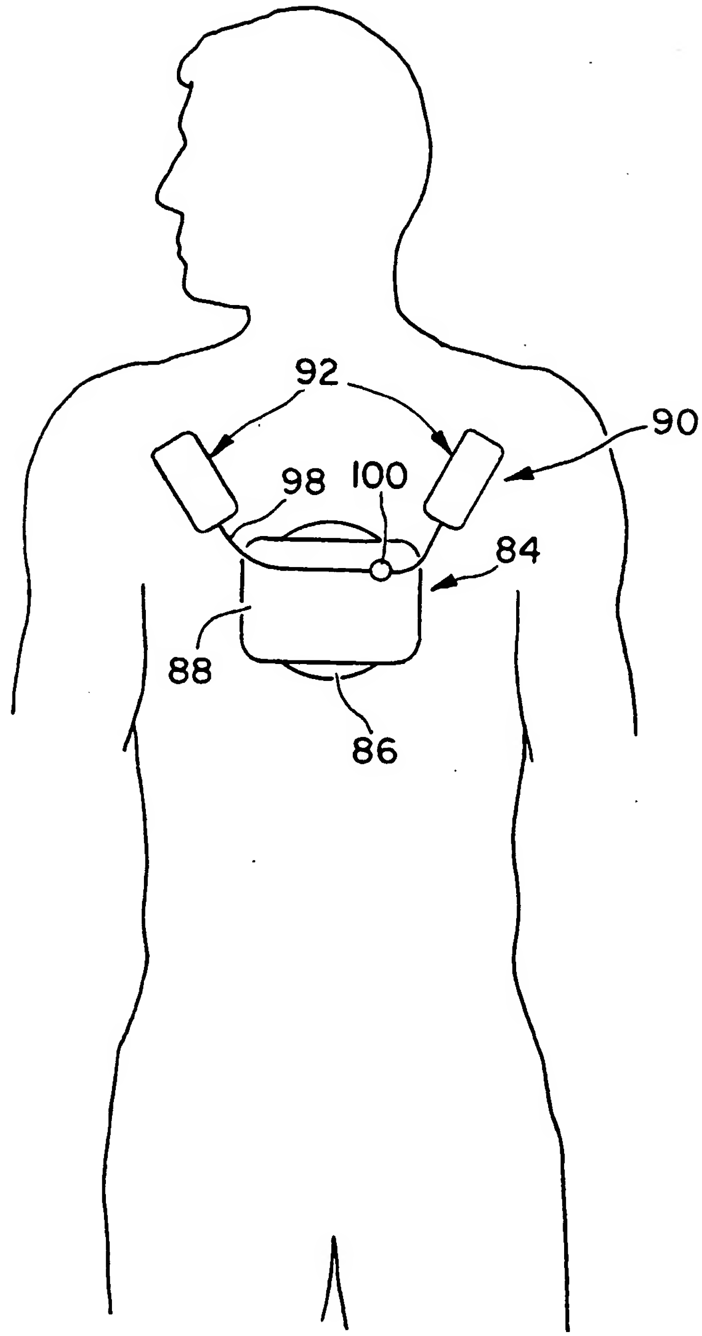
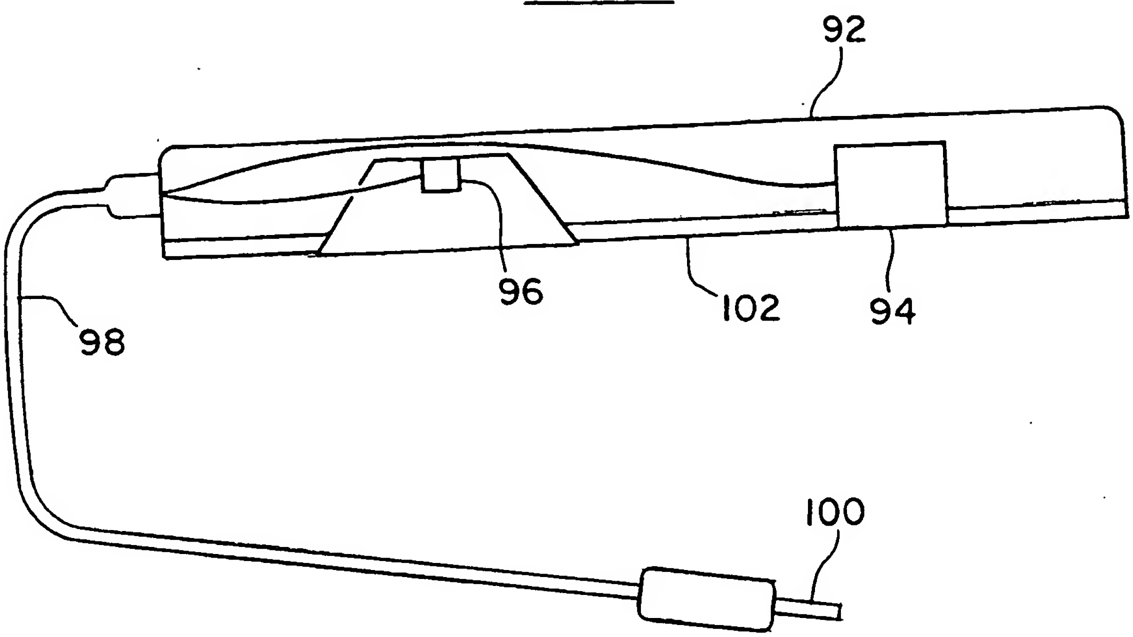


Fig. 11



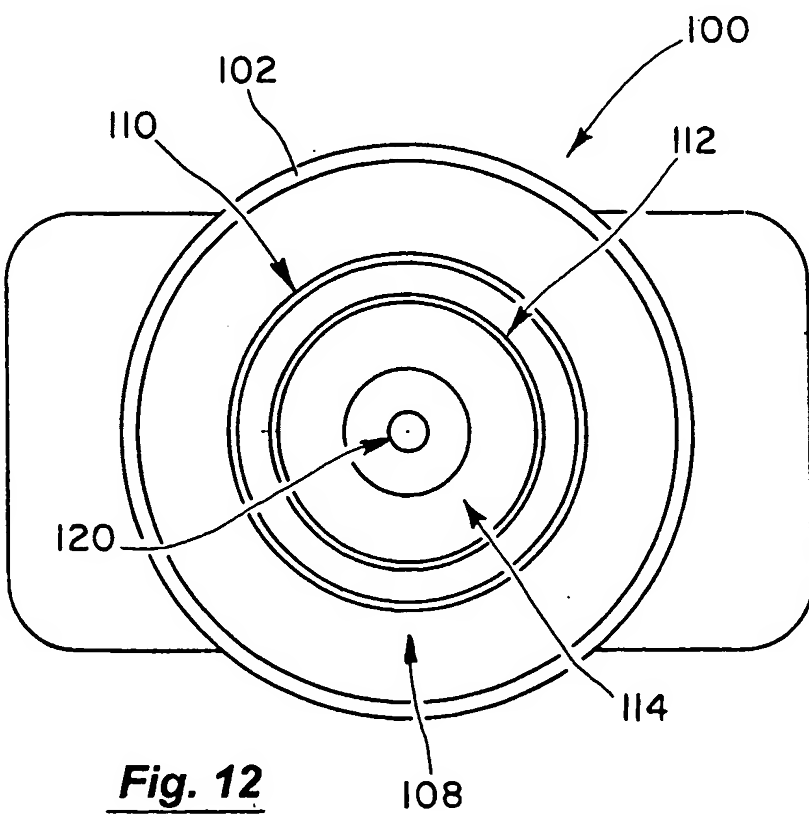


Fig. 12

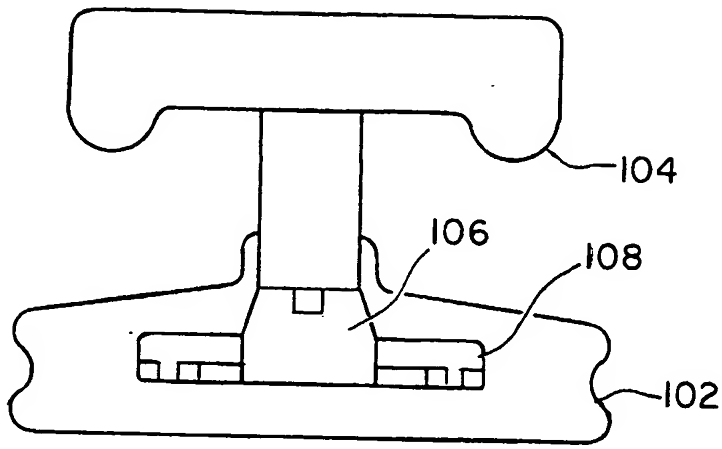


Fig. 13

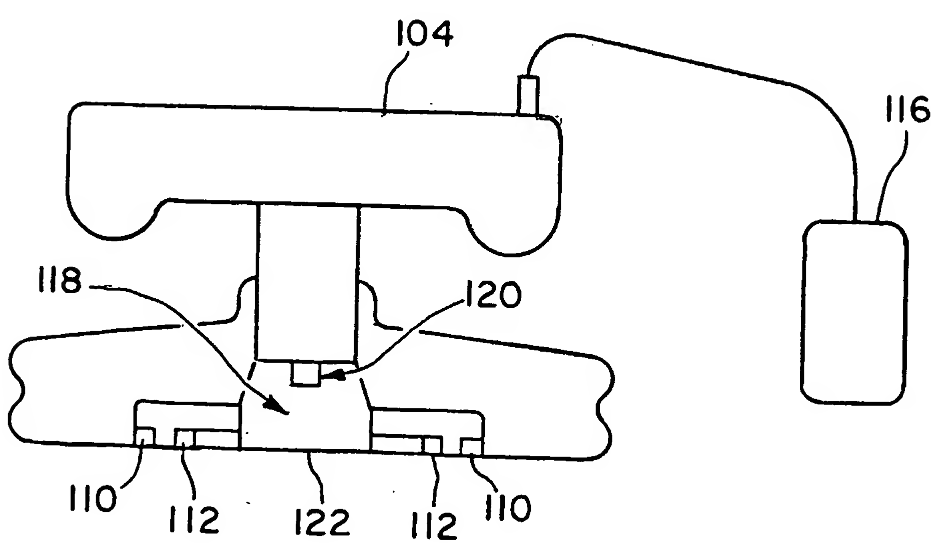
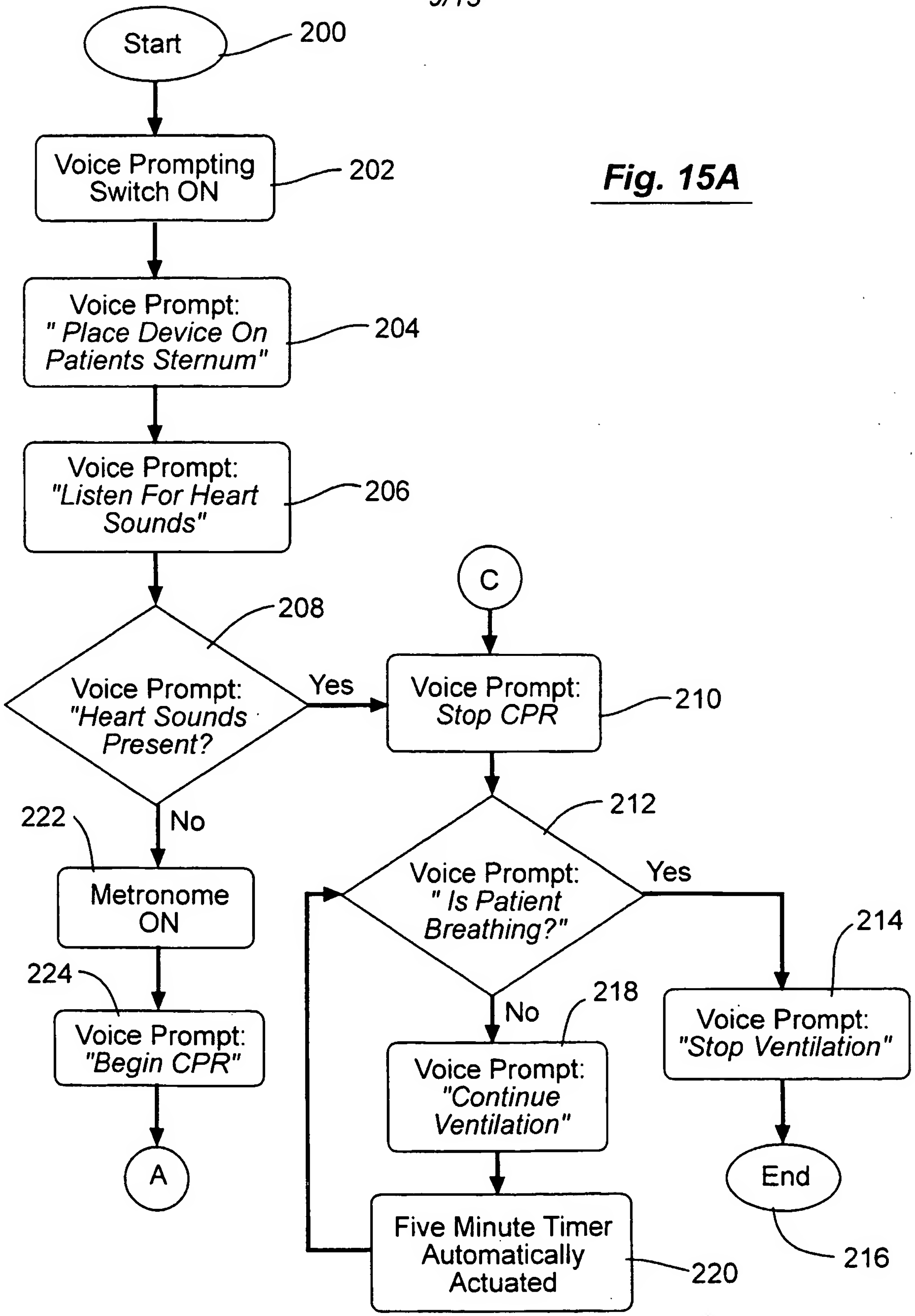


Fig. 14



Start
200
Voice Prompting Switch ON
202
Voice Prompt: " Place Device On Patients Sternum"
204
Voice Prompt: "Listen For Heart Sounds"
206
208
Voice Prompt: "Heart Sounds Present?
Yes
No
C
Voice Prompt: Stop CPR
210
212
Voice Prompt: " Is Patient Breathing?"
Yes
No
214
Voice Prompt: "Stop Ventilation"
End
216
218
Voice Prompt: "Continue Ventilation"
Five Minute Timer Automatically Actuated
220
222
Metronome ON
224
Voice Prompt: "Begin CPR"
A

Fig. 15A

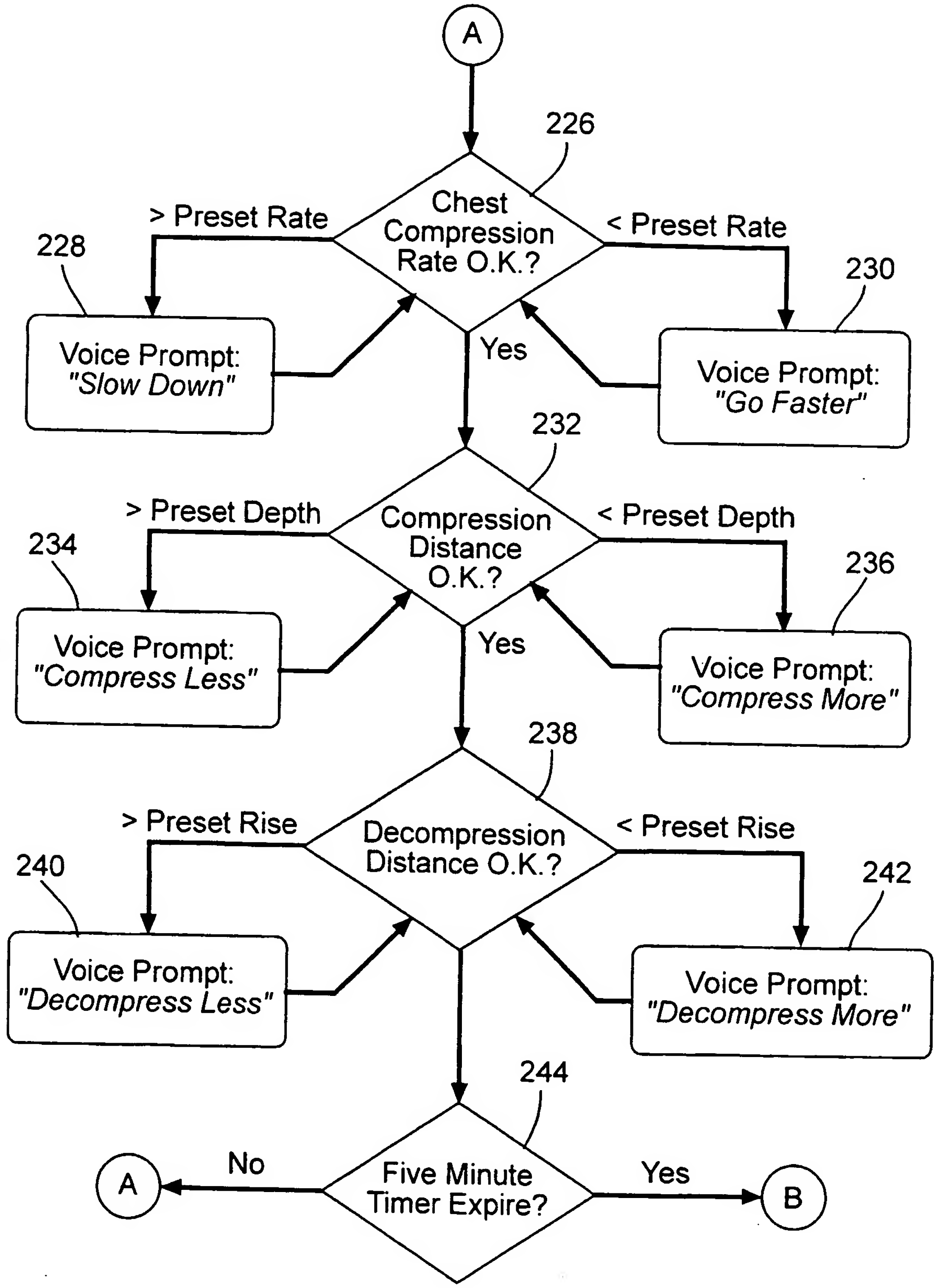

A
226
Chest Compression Rate O.K.?
> Preset Rate
< Preset Rate
228
230
Voice Prompt: "Slow Down"
Voice Prompt: "Go Faster"
Yes
232
Compression Distance O.K.?
> Preset Depth
< Preset Depth
234
236
Voice Prompt: "Compress Less"
Voice Prompt: "Compress More"
Yes
238
Decompression Distance O.K.?
> Preset Rise
< Preset Rise
240
242
Voice Prompt: "Decompress Less"
Voice Prompt: "Decompress More"
244
Five Minute Timer Expire?
No
A
Yes
B

Fig. 15B

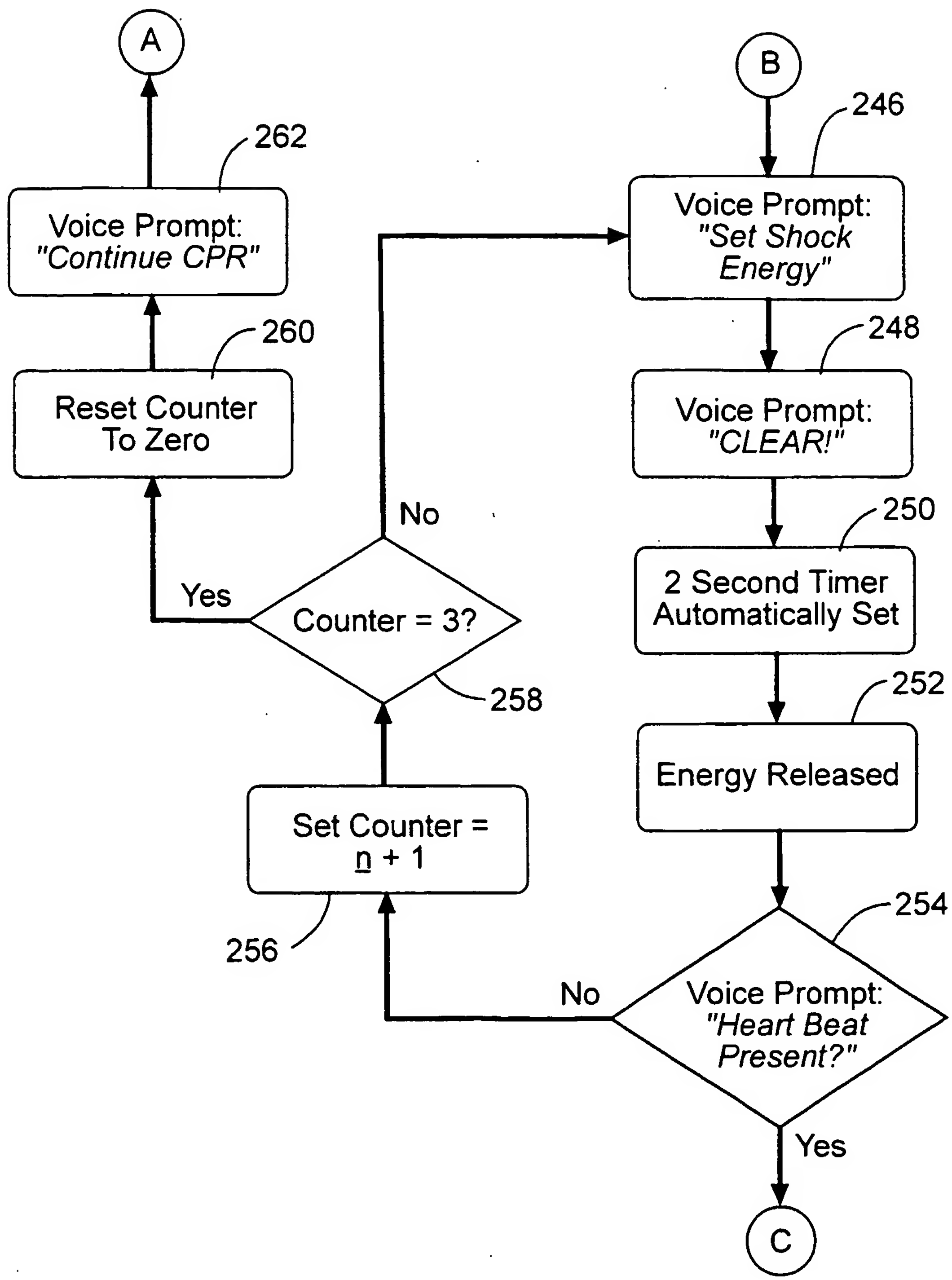

A
B
246
262
Voice Prompt:
"Continue CPR"
Voice Prompt:
"Set Shock Energy"
260
248
Reset Counter To Zero
Voice Prompt:
"CLEAR!"
No
250
Yes
Counter = 3?
2 Second Timer Automatically Set
258
252
Energy Released
Set Counter = n + 1
254
256
No
Voice Prompt:
"Heart Beat Present?"
Yes
C

Fig. 15C

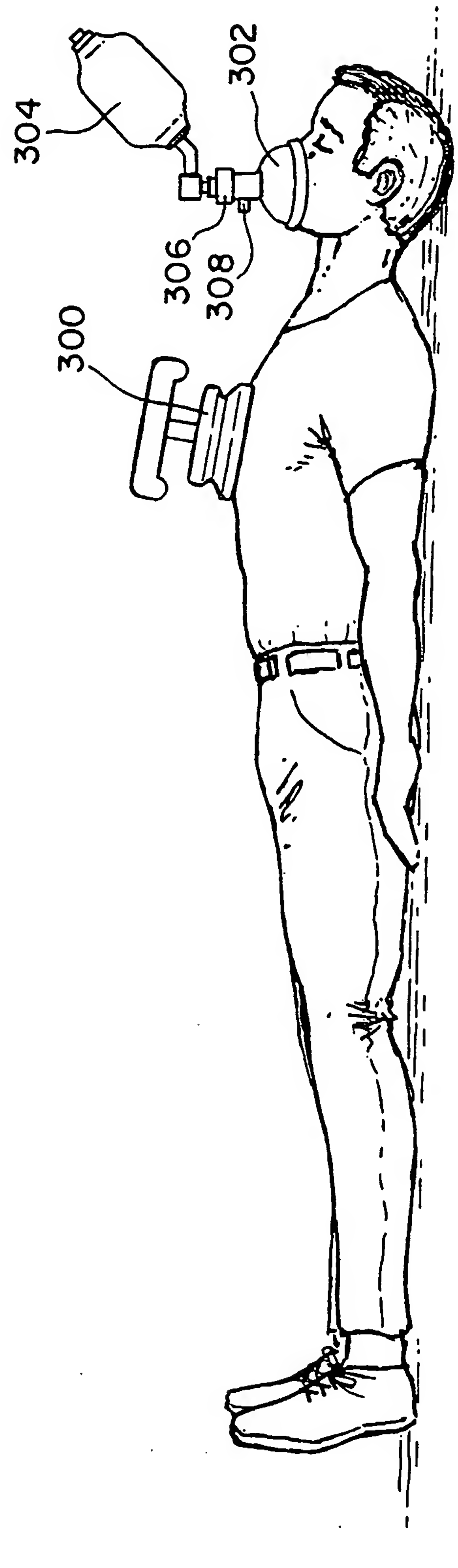


Fig. 16

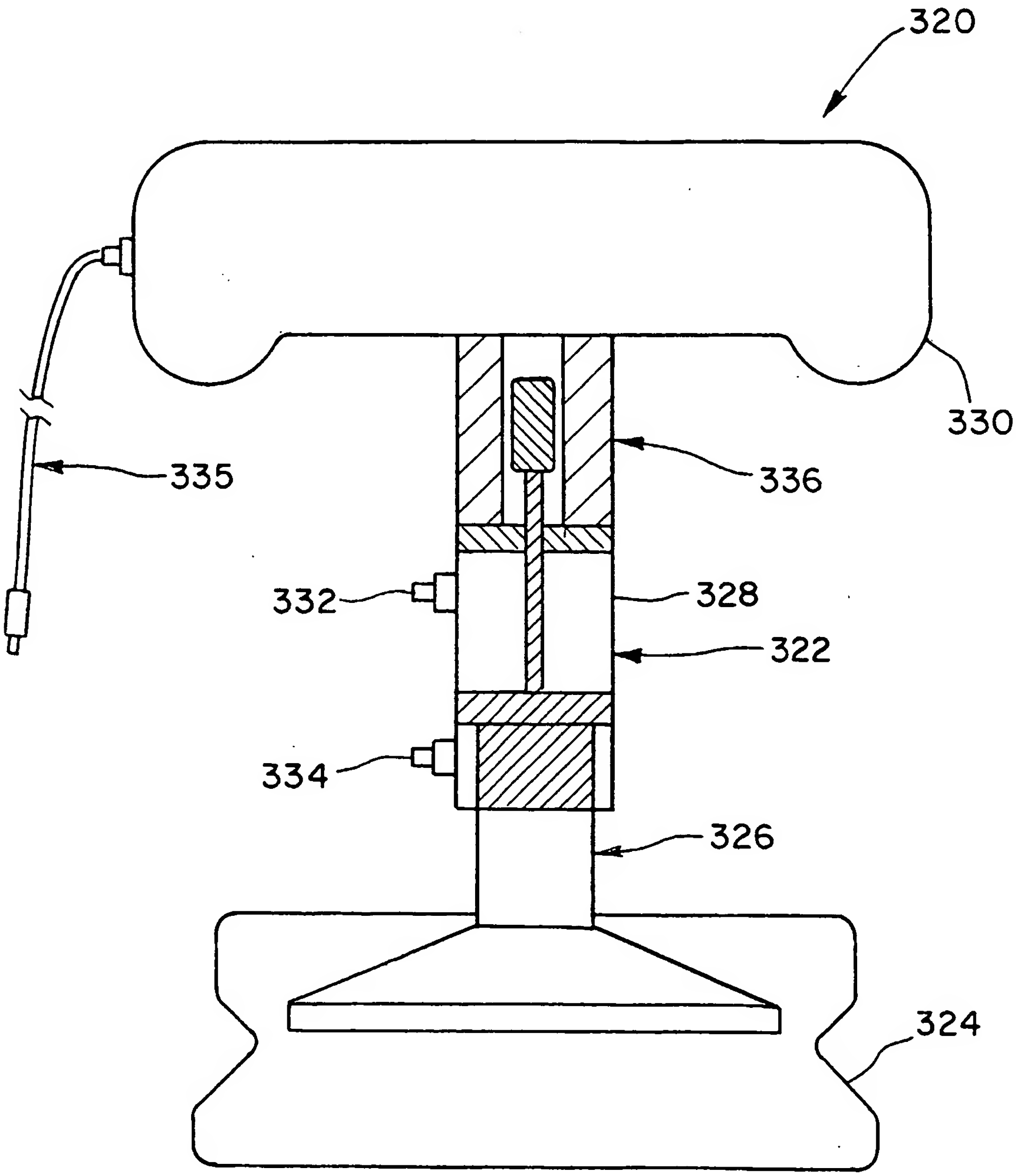


Fig. 17

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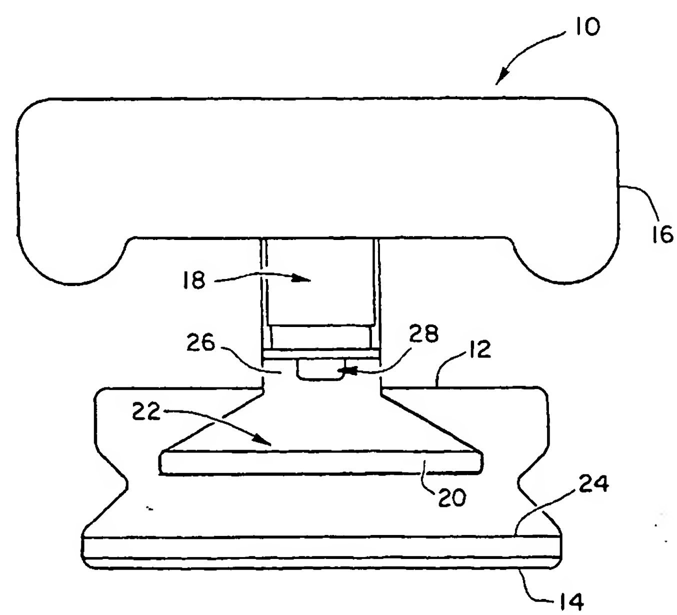
(54) Title: CARDIOPULMONARY RESUSCITATION CHEST COMPRESSION/DECOMPRESSION DEVICE WITH ELECTRONIC STETHOSCOPE



(57) Abstract: A device for performing cardiopulmonary resuscitation on a patient comprises an applicator body (12) that is configured to be adhered to the patient's chest. A handle (16) is coupled to the applicator body (12) to permit the patient's chest to be actively compressed and lifted by pressing and pulling upon the handle (16). A stethoscope system (12, 26, 28) is operably coupled to the applicator body (12) to sense the patient's heart beat and to disseminate the information on the heart beat to a rescuer.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/14038

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61H 31/00
US CL : 601/41, 43, 6, 7

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 601/41, 43, 6, 7, 9; 604/313-316

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,645,522 A (LURIE ET AL.) 08 JULY 1997 (08.07.1997) SEE ENTIRE DOCUMENT.	1, 3, 4, 10-15, 17, 18, 20, 21, 23, 24, 28-32, 34, 35, 48 ----------- 2, 5-9, 16, 19, 22, 25, 26, 27, 33, 36-47, 49
Y	US 6,210,344 B1 (PERIN ET AL) 03 APRIL 2001 (03.04.2001) SEE ENTIRE DOCUMENT.	9, 27, 33
Y	US 5,692,498 A (LURIE ET AL) 02 DECEMBER 1997 (02.12.1997) SEE ENTIRE DOCUMENT.	46, 47, 49

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search 09 September 2002 (09.09.2002)	Date of mailing of the international search report 03 APR 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Danton DeMille Telephone No. (703) 308-0858

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